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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/800,070	03/06/2001	Yves Delmotte	WM-252.00	4142
7	590 03/26/2003			
Baxter Healthcare Corporation			EXAMINER	
P.O. Box 15210 Irvine, CA 92614			WARE, TODD	
			ART UNIT	PAPER NUMBER
			1615	
			DATE MAILED: 03/26/2003	10

Please find below and/or attached an Office communication concerning this application or proceeding.

Application N. Applicatings.  Office Action Summary  Examiner	,		A college value					
Examiner		Application N .	Applicant(s)					
Todd D Ware  A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM  THE MAILING DATE OF THIS COMMUNICATION.  The period for reply specified above is base that entiry (60) days, a reply within the statutory minimum of hinly (01) days, with a considered limely.  If No period to reply specified above is base that this (60) days, a reply within the statutory minimum of hinly (01) days, with a considered limely.  If No period to reply specified above is base that this (60) days, a reply within the statutory minimum of hinly (01) days, with a considerable to the communication.  If the period for reply specified above is base that this (60) days, a reply within the statutory minimum of hinly (01) days, with a considerable to the communication.  The period for reply specified above is base that the malling date of the communication, even if timely fleed, may reduce a fine search and the statutory date of the communication.  The period today is a considerable to the communication and the statutory fleet and th		09/800,070	DELMOTTE, YVES					
Period for Reply  A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ② MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  Extensions of ten may be available under the provisions of 3 f CRF 1.13(to). In no event, however, may a reply be timely liked after SIX (b) MONTH'S from the maling date of the sooremandation and you within the statutery minimum of thinly (30) days will be considered finely.  If NO period to reply is specified sows, the maximum statutory period via long and via clipper SIX (b) MONTH'S from the realing date of his communication.  If NO period to reply is specified sows, the maximum statutory period via long and via clipper SIX (b) MONTH'S from the realing date of his communication.  Failure to reply within the set or extended period for reply vall, by statutory period via long and via clipper SIX (b) MONTH'S from the realing date of his communication.  Failure to reply within the set or extended period for reply vall, by statutor, and the specification to become ABANCHOED (SU S.C. § 133), seared patrent term edigistal rend vall by the communication.  Provided the set of the specification is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.  Disposition of Claims  4) Claim(s) 37-28 it sfare pending in the application.  4) Of the above claim(s) isfare withdrawn from consideration.  5] Claims(s) isfare allowed.  6) Claims(s) isfare objected to.  8) Claim(s) 37-28 it sfare rejected.  7) Claims(s) isfare objected to.  8) The proposed drawing correction filed on isfare: a) approved by the Examiner.  10) The drawing(s) filed on isfare: a) accepted or b) disapproved by the Examiner.  If approved, corrected drawings are required in reply to this Office action.  12) The proposed drawing correction filed on isfare: a) approved by disapproved by the Examiner.  If approved, corrected drawings are require	Office Action Summary	Examiner	Art Unit					
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  Extensions of time-ray be available under the provisions of 37 °FR 1.35(s). In no event, however, may a reply be timely filed  Extensions of time-ray be available under the provisions of 37 °FR 1.35(s). In no event, however, may a reply be timely filed  Extensions of time-ray be available under the provisions of 37 °FR 1.35(s). In no event, however, may a reply be timely filed  Extensions of time-ray be available under the provisions of 37 °FR 1.35(s). In no event, however, may a reply be timely filed.  Extensions of time-ray be available under the provisions of 37 °FR 1.35(s). In no event, however, may a reply be timely filed.  If No period for ray's period advision is a possible under the filed under the solid under the s								
THE MAILING DATE OF THIS COMMUNICATION.  Extensions of time may be available under the provisions of 3 CFR 1.15(6). In no event, however, may a reply be timely lited after SIX (8) MONTHS from the mailing date of this communication.  I shall be compared to the provision of the communication of the commu		ears on the cover shee	with the correspondence address					
2a)  This action is FINAL. 2b  This action is non-final.  3  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.  Disposition of Claims  4)  Claim(s) 37-84 is/are pending in the application.  4a) Of the above claim(s)	<ul> <li>THE MAILING DATE OF THIS COMMUNICATION.</li> <li>Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.</li> <li>If the period for reply specified above is less than thirty (30) days, a reply If NO period for reply is specified above, the maximum statutory period we Failure to reply within the set or extended period for reply will, by statute,</li> <li>Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).</li> </ul>	36(a). In no event, however, may within the statutory minimum of vill apply and will expire SIX (6) No cause the application to become	v a reply be timely filed thirty (30) days will be considered timely. SONTHS from the mailing date of this communication. ABANDONED (35 U.S.C. § 133).					
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#### **DETAILED ACTION**

Receipt of request for extension of time, information disclosure statement, and amendment all filed 11-19-02 is acknowledged. Claims 1-36 have been canceled and new claims 37-84 have been added. Claims 37-84 are pending.

### Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 2. Claims 37-40, 44-45, 48-50, 52, 56-58, 62-64, 66-69, 72, 75, 77-79, 81-84 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Sawamoto et al (5,298,255; hereafter '255).
- 3. '255 discloses porous antithrombic stents comprising fibrin formed with fibrinogen and the instant process for their making.

## Response to Arguments

4. Applicant's arguments filed 11-19-02 have been fully considered but they are not persuasive. Applicant argues that the instant claims are not anticipated by '255 since the instant claims require at least a portion stretched in at least one longitudinal stretching direction and asserts that '255 does not disclose this. This argument is not found persuasive. '255 discloses stretching of the fibrin and this appears to be just a matter of phraseology (i.e. instant claims do not differentiate what stretching is

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longitudinal to what –longitudinal is in reference to something what one person refers in reference to is not what another refers in reference to).

- 5. Claims 37-40, 44, 48-50, 52, 56-58, 62-69, 72-84 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Dinh et al (5,510,077; hereafter '077) or Dinh (5,591,227; hereafter '227).
- 6. '077 and '227 both disclose porous antithrombic stents comprising fibrin formed with fibrinogen and administration of an active agent with the stent. '077 and '227 also disclose the instant process for their making.

### Response to Arguments

7. Applicant's arguments filed 11-19-02 have been fully considered but they are not persuasive. Applicant argues that the instant claims are not anticipated by '077 or '227 since the instant claims require at least a portion stretched in at least one longitudinal stretching direction and asserts that '077 and '227 do not disclose this. This argument is not found persuasive. Column 9, line 20 of '227 and column 8, lines 20-22 for example, specifically state that the fibrin is longitudinally stretched.

## Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

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- 9. Claims 37-87 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sawamoto et al (5,298,255; hereafter '255) or Dinh et al (5,510,077; hereafter '077) or Dinh (5,591,227; hereafter '227).
- 10. '255, '077 and '227 all disclose porous antithrombic stents comprising fibrin formed with fibrinogen and the instant process for their making. '077 and '227 also teach administration of an active agent with the stent. The references do no specify the degree of difference between densities, however it is submitted that it would have been obvious to one skilled in the art at the time of the invention to achieve the instant claimed density differences based upon the motivation of providing different thickness, degree of mechanical properties and biostability of the device. Also, it would have been obvious to one skilled in the art at the time of the invention to utilize different diameter stents based upon the blood vessel diameter where the stent is to be used and the provide a wall thickness that would be thick enough to withstand tearing during stretching, but thin enough to allow material to pass through the stent without being too large to place in a blood vessel. Amounts of thrombin would have been obvious to one skilled in the art at the time of the invention with the motivation of providing sufficient thrombin to convert fibrinogen to fibrin.

## Response to Arguments

11. Applicant's arguments filed 11-19-02 have been fully considered but they are not persuasive. Applicant argues that the instant claims are not obviated by '255, '077, or '227 since the instant claims require at least a portion stretched in at least one longitudinal stretching direction and asserts that '255, '077 and '227 do not teach this.

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This argument is not found persuasive. Column 9, line 20 of '227 and column 8, lines 20-22 for example, specifically state that the fibrin is longitudinally stretched. Furthermore, stretching of the fibrin appears to be just a matter of phraseology (i.e. instant claims do not differentiate what stretching is longitudinal to what –longitudinal is in reference to something what one person refers in reference to is not what another refers in reference to).

#### Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Todd D Ware whose telephone number is (703) 305-

1700. The examiner can normally be reached on M-F, 8:30 AM - 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Thurman K Page can be reached on (703)308-2927. The fax phone

numbers for the organization where this application or proceeding is assigned are (703)

308-4556 for regular communications and (703) 308-4556 for After Final

communications.

Any inquiry of a general nature or relating to the status of this application or

proceeding should be directed to the receptionist whose telephone number is (703) 308-

1234.

tw

March 24, 2003

THURMAN/K. PAGE SUPERVISORY PATENT EXAMINER TECHNOLOGY/CENTER 1600